

REMARKS

Claims 1, 4-22, 24, and 26-28 remain in the application. Claims 1, 4-10, 15, 16, 20-22, 24, and 26-28 have been amended. A version with markings to show changes made follows page 17. Claims 29-62 have been added. Claims 2, 3, 23, and 25 have been cancelled. Reconsideration of this application, as amended, is respectfully requested.

The characteristics of the amendments and newly added claims will now be described.

- (1) The subject matter of claim 2 was incorporated into claim 1.
- (2) Claim 4 was rewritten in independent form.
- (3) Claim 5 was rewritten to conform to claim 4.
- (4) Claim 6 was rewritten in independent form.
- (5) Claims 7 and 8 were rewritten to conform to claim 6.
- (6) Claim 9 was rewritten in independent form.
- (7) Claim 10 was amended to depend from claim 1.
- (8) In claim 15, the expression "one or more reagents" was rewritten as "at least one reagent".
- (9) In claim 16, the expression "said reagent" was rewritten as "said at least one reagent".
- (10) Claims 20 and 21 were rewritten to conform to claim 1.
- (11) Claim 22 was amended to depend from claim 1. In claim 22, the test port was described as "comprising at least two electrically conductive pins, said at least two electrically conductive pins capable of specifically interacting with said at least one electrically conductive indicator contact on said test strip, thereby selecting at least one of said multiplicity of testing functionalities of said measuring device."
- (12) Claim 24 was amended to depend from claim 22. Also, in claim 24, the word "indicators" was rewritten as "at least one electrically conductive indicator contact".
- (13) Claim 26 was amended to depend from claim 4. In claim 26, it was recited that the test port "comprises at least one pin that can be

mechanically engaged by said indicator on said test strip, thereby either closing an electrical circuit or opening an electrical circuit."

(14) Claim 27 was amended to depend from claim 9. In claim 27, it was recited that the test port "comprises at least one optical sensor capable of measuring light absorbance, reflectivity, color, or a character."

(15) Claim 28 was amended to depend from claim 1. In claim 28, the test port was described as "comprising at least two electrically conductive pins, said at least two electrically conductive pins capable of specifically interacting with said at least one electrically conductive indicator contact on said test strip, thereby selecting at least one of said multiplicity of testing functionalities of said measuring device."

(16) Claim 29 was added to recite a test port analogous to the test port claimed in claim 26, but depending from claim 6. In claim 29, it was recited that the test port "comprises a pattern of at least one indentation or hole, wherein said at least one indentation or hole fails to displace at least one pin of said test strip upon insertion of said test strip into said test port, thereby selecting at least one of said multiplicity of testing functionalities of said measuring device."

(17) Claims 30-39, inclusive, were added to recite the subject matter of claims 12-21, respectively, but depending directly or indirectly from claim 4.

(18) Claim 40 was added to claim a measuring device analogous to the measuring device claimed in claim 28, but depending from claim 6. In claim 40, the test port was described as "comprising at least one pin that can be mechanically engaged by said indicator on said test strip, thereby either closing an electrical circuit or opening an electrical circuit."

(19) Claims 41-50, inclusive, were added to recite the subject matter of claims 12-21, respectively, but depending directly or indirectly from claim 6.

(20) Claim 51 was added to recite a measuring device analogous to the measuring device claimed in claim 28, but depending from claim 6. In claim 51, the test port was described as "comprising a pattern of at least one indentation or hole, wherein said at least one indentation or hole fails to displace at least one pin of said test strip upon insertion of said test strip into said test port, thereby selecting at least one of said multiplicity of testing functionalities of said measuring device."

(21) Claims 52-61, inclusive, were added to recite the subject matter of claims 12-21, respectively, but depending directly or indirectly from claim 9.

(22) Claim 62 was added to claim a measuring device analogous to the measuring device claimed in claim 28, but depending from claim 9. In claim 62, the test port was described as "comprising at least one optical sensor capable of measuring light absorbance, reflectivity, color, or a character."

(23) In claims 4-8 and 15, the expression "one or more" was rewritten as "at least one".

Claims 1-3, 9, 10, 12-18, 21-24, 27, and 28 stand rejected under 35 U. S. C. § 102 (b) as being anticipated by US Patent 5,580,794 to Allen. This rejection is respectfully traversed for the following reasons.

Allen, U. S. Patent No. 5,580,794 (hereinafter "Allen"), discloses a disposable electronic assay device comprising card-like housing containing a sample receptor means for receiving a sample of body fluid containing an analyte to be determined, a sample treatment means for reaction with sample fluid components to yield a physically detectable change which correlates with the amount of analyte in the sample, a detector means responsive to the physically detectable change for producing an electrical signal which correlates with the amount of analyte in the sample, signal processing means connected to the detector means for converting the electrical signal to a digital test result output, and visually readable output means connected to the signal processor means for receiving and presenting the test result output.

The present invention provides products wherein a user may perform a multiplicity of different assays with a single measuring device having a multiplicity of testing functionalities, without the need for manually reconfiguring or switching between different functionalities of the device. By eliminating the need for the user to manually set the device when changing from one testing functionality to another, the invention provides increased convenience and speed of use, and reduces the likelihood of human error. The invention employs a multichemistry test port that is capable of recognizing various diagnostic test strips having different testing functionalities. Each type of diagnostic test strip comprises a different indicator (or indicators) that enable the test port to differentiate one type of

diagnostic test strip from other types of diagnostic test strips. When the user inserts the diagnostic test strip into the test port of the measuring device, the test port will identify the appropriate functionality of the measuring device and automatically reconfigure or switch the measuring device to the appropriate functionality. See page 7, lines 3-17 of the specification. Specific types of indicators are described at page 9, line 27 through page 11, line 7 of the specification. Test ports for interacting with the diagnostic test strips are described at page 11, line 9 through page 12, line 20 of the specification. Neither of the references relied on by the Examiner disclose or suggest the test strips or the test ports of the type claimed in this application.

At column 6, lines 48-52 of Allen, it is stated:

Single or multiple assays can be done at one time. For example, a single assay can be done measuring cholesterol or one device can be set up to measure both total and HDL cholesterol from a single sample. One test device can be set up to measure one, two, three, or more analytes **at one time**.
(emphasis added)

This statement does not disclose or suggest an indicator on a test strip that can allow a measuring device to differentiate between two or more types of test strips to select at least one of a multiplicity of testing functionalities of the measuring device. This statement does not disclose or suggest a test port (of a measuring device) having a sensor that can select at least one of a multiplicity of testing functionalities of the measuring device. This statement proves that the device and the test strips described in Allen cannot cooperate to differentiate between two or more types of assays, but must perform all of the assays on a test strip at the same time. In Example 1 of Allen, it is shown that more than one assay on the test strip can be carried out at the same time. However, the test strip and the test port in Allen cannot communicate to select a particular assay to be performed at a particular time. In Allen, all of the assays in a given set of assays must be carried out at the same time. In view of the foregoing, it is submitted that Allen does not anticipate any claim of this application.

Claims 1-8, 10-26, and 28 stand rejected under 35 U. S. C. § 102 (b) as being anticipated by US Patent 5,312, 590 to Gunasingham. This rejection is respectfully traversed for the following reasons.

Gunasingham, U. S. Patent No. 5,312,590 (hereinafter "Gunasingham"), discloses a method and apparatus for measuring a wide range of chemical species in liquids. The apparatus employs a flat test device comprising a number of symmetrically arranged sensor elements that enable the multi-species determination from a single sample drop. Each sensor element is coated with a unique reaction layer that makes it responsive to specific chemical species. Additionally, all the sensor elements are coated with a single membrane which serves the dual function of a diffusion barrier and filter. An insulating layer is further coated over the membrane with specific provision for wells where the sample and reference solutions may be placed/. In a preferred embodiment of the invention, the sample well is centrally located so that chemical species present in the sample can diffuse equally to the various sensing elements. The reference solution wells are located adjacent to the specific sensing element. The center of the sample solution well and the center of the reference solution well are equidistant to the respective sensing element so that the diffusion of chemical species from the sample and reference solutions occurs equally.

As stated previously, each type of diagnostic test strip claimed in the present application comprises a different indicator (or indicators) that enable the test port to differentiate one type of diagnostic test strip from other types of diagnostic test strips. When the user inserts the diagnostic test strip into the test port of the measuring device, the test port will identify the appropriate functionality of the measuring device and automatically reconfigure or switch the measuring device to the appropriate functionality.

At column 8, lines 24-44 of Gunasingham, multi-species detection is described. This mode of detection was described as follows:

The device consists of four symmetrically arranged sensor elements (16) that enable multi-species determination from a single sample drop. Each sensor element is coated with a unique reaction layer (17) that makes it responsive to specific

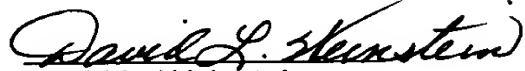
chemical species. Additionally, all the sensor elements are coated with a single membrane (18) which serves the dual function of a diffusion barrier and filter. An insulating layer (19) is further coated over the membrane with specific provision for wells where the sample (20) and reference solutions (21) may be placed. The sample well is centrally located so that chemical species present in the sample can diffuse equally to the various sensing elements. The reference solution wells are located adjacent to the specific sensing element. The center of the sample solution well and the center of the reference solution well are equidistant to the respective sensing element so that **the diffusion of chemical species from the sample and reference solutions occurs equally.** (emphasis added)

This statement does not disclose or suggest an indicator on a test strip that can allow a measuring device to differentiate between two or more types of test strips to select at least one of a multiplicity of testing functionalities of the measuring device. This statement does not disclose or suggest a test port (of a measuring device) having a sensor that can select at least one of a multiplicity of testing functionalities of the measuring device. This statement proves that the device and the test strips described in Gunasingham cannot cooperate to differentiate between two or more types of assays, but must perform all of the assays on a test strip at the same time. In Example 4 of Gunasingham, it is shown that more than one assay can be carried out at the same time. However, the test strip and the test port in Gunasingham cannot communicate to select a particular assay to be performed at a particular time. In Gunasingham, all of the assays in a given set of assays must be carried out at the same time. In view of the foregoing, it is submitted that Gunasingham does not anticipate any claim of this application.

In view of the foregoing, it is submitted that claims 1, 4-22, 24, and 26-62 are in condition for allowance, and official Notice of Allowance is respectfully requested.

Abbott Laboratories
D-377 AP6D-2
100 Abbott Park Road
Abbott Park, Illinois 60064-3500
Telephone: (847) 937-6182

Respectfully submitted,
M. E. Lewis, et al.


David L. Weinstein
Registration No. 28, 128
Attorney for Applicants

VERSION WITH MARKINGS TO SHOW CHANGES MADE

Kindly rewrite claims 1, 4-10, 15, 16, 20-22, 24, and 26-28 as follows:

1. (Once amended) A test strip for chemical analysis of a sample, adapted for use in combination with a measuring device having a test port and capable of performing a multiplicity of testing functionalities, said test strip comprising:

- (a) a support capable of releasably engaging said test port;
- (b) at least one reaction area on said support for receiving said sample; and
- (c) an indicator capable of interacting with said test port to select at least one of said multiplicity of testing functionalities of said measuring device, wherein said indicator comprises at least one electrically conductive indicator contact capable of engaging at least two electrically conductive pins within said test port, thereby selecting at least one of said multiplicity of testing functionalities of said measuring device.

4. (Once amended) [The test strip of claim 1] A test strip for chemical analysis of a sample, adapted for use in combination with a measuring device having a test port and capable of performing a multiplicity of testing functionalities, said test strip comprising:

- (a) a support capable of releasably engaging said test port;
- (b) at least one reaction area on said support for receiving said sample; and
- (c) an indicator capable of interacting with said test port to select at least one of said multiplicity of testing functionalities of said measuring device, wherein said indicator comprises [one or more projections] at least one projection on said support, said at least one projection capable of mechanically engaging [one or more pins] at least one pin within said test port, thereby selecting at least one of said multiplicity of testing functionalities of said measuring device.

5. (Once amended) The test strip of claim 4, wherein said [projections displace one or more of said pins] at least one projection displaces said at least one pin.

6. (Once amended) [The test strip of claim 1] A test strip for chemical analysis of a sample, adapted for use in combination with a measuring device having a test port and capable of performing a multiplicity of testing functionalities, said test strip comprising:

- (a) a support capable of releasably engaging said test port;
- (b) at least one reaction area on said support for receiving said sample; and
- (c) an indicator capable of interacting with said test port to select at least one of said multiplicity of testing functionalities of said measuring device, wherein said indicator comprises [one or more depressions] at least one depression on said support , said at least one depression capable of mechanically engaging [one or more pins] at least one pin within said test port, thereby selecting at least one of said multiplicity of testing functionalities of said measuring device.

7. (Once amended) The strip of claim 6, wherein [one or more] at least one of said pins [may] can be displaced into at least one of said depressions.

8. (Once amended) The test strip of claim 6, wherein said [depressions define one or more holes] at least one depression defines at least one hole.

9. (Once amended) [The test strip of claim 1] A test strip for chemical analysis of a sample, adapted for use in combination with a measuring device having a test port and capable of performing a multiplicity of testing functionalities, said test strip comprising:

- (a) a support capable of releasably engaging said test port;
- (b) at least one reaction area on said support for receiving said sample; and

(c) an indicator capable of interacting with said test port to select at least one of said multiplicity of testing functionalities of said measuring device, wherein said indicator comprises an optically detectable pattern capable of signaling or being detected by an optical detector in said test port, thereby selecting at least one of said multiplicity of testing functionalities of said measuring device.

10. (Once amended) The test strip of claim [2] 1, wherein said indicator contacts comprise a material selected from the group consisting of carbon, gold, silver, platinum, nickel, palladium, titanium, copper, and lead.

15. (Once amended) The test strip of claim 1, wherein said reaction area comprises [one or more reagents] at least one reagent adsorbed to said support, said at least one reagent capable of reacting with a compound in said sample.

16. (Once amended) The test strip of claim 15, wherein said at least one reagent is selected from the group consisting of glucose oxidase, lactate dehydrogenase, peroxidase, and galactose oxidase.

20. (Once amended) The test strip of claim 17, wherein said testing contacts are located on a first major surface of said test strip and said [indicator contacts are] indicator is located on a second major surface of said test strip.

21. (Once amended) The test strip of claim 17, wherein said testing contacts and said indicator [contacts] are located on the same surface of said test strip.

22. (Once amended) A test port for use in a measuring device capable of performing a multiplicity of testing functionalities and adapted for use [in combination] with [a multiplicity of different types of test strips, each of said types of test strips corresponding to at least one of said testing functionalities, and at least some of said types of test strips having indicators

of said testing functionality thereon] the test strip of claim 1, said test port comprising [a sensor] at least two electrically conductive pins, said at least two electrically conductive pins capable of specifically interacting with said [indicators] at least one electrically conductive indicator contact on said test [strips] strip, thereby selecting at least one of said multiplicity of testing functionalities [corresponding to a test strip] of said measuring device.

24. (Once amended) The test port of claim [23] 22, wherein at least two of said electrically conductive pins [may] can be bridged by said [indicators] at least one electrically conductive indicator contact, thereby closing an electrical circuit.

26. (Once amended) [The test port of claim 25] A test port for use in a measuring device capable of performing a multiplicity of testing functionalities and adapted for use with the test strip of claim 4, wherein [at least a portion of said mechanical sensor may be physically displaced by said indicators] said test port comprises at least one pin that can be mechanically engaged by said indicator on said test strip, thereby either closing an electrical circuit or opening an electrical circuit.

27. (Once amended) [The test port of claim 22] A test port for use in a measuring device capable of performing a multiplicity of testing functionalities and adapted for use with the test strip of claim 9, wherein [said indicators are optically detectable and] said test port comprises at least one optical sensor capable of measuring light absorbance, reflectivity, color, or a character [said sensor is an optical sensor].

28. (Once amended) A measuring device having a multiplicity of testing functionalities for chemical analysis, adapted for use [in combination] with [a multiplicity of different types of test strips, each of said types of test strips corresponding to at least one of said testing functionalities, and at least some of said types of test strips having indicators of said testing functionality thereon] the test strip of claim 1, said device comprising:

(a) a test port comprising [a sensor capable of interacting with said indicators on said test strips to select at least one of said multiplicity of testing functionalities] at least two electrically conductive pins, said at least two electrically conductive pins capable of specifically interacting with said at least one electrically conductive indicator contact on said test strip, thereby selecting at least one of said multiplicity of testing functionalities of said measuring device; and

(b) a multiplicity of test circuitries for specifically measuring reactions on said test [strips] strip, said multiplicity of said test circuitries corresponding to said multiplicity of testing functionalities.